



# ANALYTICAL RESEARCH LABORATORIES

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## Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01

LOT #: 05212012@68

DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection

DATE RECEIVED: 05/22/2012

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

*Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.*

*Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.*

*Endotoxin - To calculate the endotoxin limit use the following formulae:  $EL = K/M$  where  $K$  = tolerance limit (EU/kg) and  $M$  = Maximum dose/kg/hour or Maximum dose/kg*

*Parenteral:  $K$  is 5 EU/kg for any route of administration (Intrathecal:  $K$  is 0.2 EU/kg body weight)*

*Radiopharmaceutical parenteral:  $K$  is  $175/V$  or Intrathecal radiopharmaceuticals:  $K$  is  $14/V$ , where  $V$  is the maximum recommended dose in mL.*

*Dermal Application:  $K/M$ , where  $K$  = 5 EU/kg and  $M$  is the (maximum dose/m<sup>2</sup>/hour  $\times$  1.80 m<sup>2</sup>)/70 Kg.*

05/25/2012

- Microbiologist

Date Reported

ARL Form QUF-078-V4 03/03/2010

Results reported above relate only to the sample that was tested.